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10/559,794	12/08/2005	Federico Mailland	622-89	7507

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EXAMINER

ANDERSON, HEATHER L

ART UNIT	PAPER NUMBER
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1655

MAIL DATE	DELIVERY MODE
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10/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/559,794

Applicant(s)

MAILLAND, FEDERICO

Examiner

Heather Anderson

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/08/2005 and 01/31/2006.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Claims 1-24 have been cancelled. Claims 25-47 are presented for examination on the merits.

Claim Objections

Claims 25, 33 and 46 are objected to because of the following informalities: typographical errors of "needs" instead of "need" in claim 25, "derivatized" instead of "derived" in claim 33, "gene" instead of "genus" in claim 46, and lack of component a) in claim 46. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28, 33-38 and 41-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat.

App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 28 recites the broad recitation of component a) possibly being selected from either *Equisetum arvense* or *Equisetum hiemale* in form of plant or part of plant. Claim 28 also recites that it depends on claim 25, which requires component a) to be "at least one herb extract from the genus *Equisetum*," which is the narrower statement of the range/limitation.

Furthermore, claims 33, 34 and 37 all recite the broad recitation of groups of chemical compounds with a ranges of numbers of both carbon atoms and various constituents, and the claims also all recite that certain particular chemical compounds in those groups are "preferable," which is the narrower statement of the range/limitation. Additionally, in each of claims 41-45, two different ranges of percent weights of various components recite are recited. First the larger, broad range is recited, and then a smaller, "more preferable" range within the first larger range is recited, which is the narrower statement of the range/limitation.

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Claims 35, 38, 43 and 45 recite limitations for components c) and d) and all of these claims depend on claim 25. There is insufficient antecedent basis for this limitation in the claim because there are no components c) and d) in claim 25, only a) and b).

Claim 44 depends on claim 43, which depends on claim 25. Claim 44 recites the limitation "~~the~~ water content" in component c), but water is not mentioned in either of the two preceding claims. Thus, there is insufficient antecedent basis for this limitation in the claim.

Claim 36 depends directly or indirectly from rejected claims and is therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over PDR® for Herbal Medicines (1998) and Koniger et al. (WO 94/25041, Derwent abstract and Machine Translation provided) in view of Ramin (JP 07-285830, translated as US 5,667,768) and Trimuyadi et al. (Conference of the Asian Societies, 2001).

A method for treatment of onychoschizia (splitting nails) comprising the administration of a topical composition with certain components, including Equisetum extract, is claimed. Dependent claims include further limitations of the components.

PDR® for Herbal Medicines beneficially teaches the well-known usage of Equisetum (horsetail) for brittle fingernails (see, e.g., page 831, column 2, third paragraph and entire entry). Under "Mode of Administration" in the same column, comminuted herbal decoctions (water extraction) or other galenic preparations (i.e., other solvents and/or methods of extraction) are described for external (topical) use.

Koniger et al. beneficially teach the topical use of Equisetum extracts (see, e.g., abstract and entire document). On page 3, paragraph 3 of the machine translated text, the use of Equisetum extract for the treating fungal infections of the fingernail is described. Aqueous isopropanol is identified as a carrier in this composition, which is applied as a thin film to the surface of the nail. As applicant readily admits on page 21, Example 10 of the instant specification, fungal infections (onychomycosis) are well known in the art to cause splitting and other damage to the nail, such that applicant included women with this condition in their own clinical study. Neither of the above references explicitly teaches chitosan as the film-forming agent or adding a sulfur donor.

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Ramin beneficially teaches beneficially applying a composition to the nails for restructuring and reducing splitting (see, e.g., abstract and entire document). Additional active ingredients include cysteine (a sulfur donor), chitosan and its derivatives, antifungal and antibacterial agents. Trimulyadi et al. beneficially teach the use of chitosan as a film-forming agent in nail polish (see, e.g., the abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer Equisetum extract in combination with several other known nail strengthening agents as a topical application on the nail surface for the treatment of splitting, brittle nails based upon the beneficial teachings provided by the cited references, as discussed above. The adjustment of particular conventional working conditions (e.g., selecting active ingredients and carriers and/or determining a suitable ratios of components for the most effective treatment) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

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The following prior art considered pertinent to applicant's disclosure is not relied upon but is hereby made of record. US 2004/0013622 teaches the use of a composition comprising horsetail (*Equisetum*) extract for improving nail health. US 7,033,578 teaches a nail varnish composition comprising an antimycotic agent (which may be selected from plant extracts), a water soluble film-forming agent such as chitosan or its derivatives, a water based solvent, and other possible active ingredients for the treatment of onychomycosis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather Anderson whose telephone number is (571) 270-3051. The examiner can normally be reached on Monday-Thursday, 7:30 AM-5:00 PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry KcKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HLA



CHRISTOPHER R. TATE
PRIMARY EXAMINER